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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/759,811

01/16/2004

Patrick Miles

039US1

8249

30328 7590 06/05/2007
JONATHAN SPANGLER
NU VASIVE, INC.
4545 TOWNE CENTRE COURT
SAN DIEGO, CA 92121

EXAMINER

WERNER, JONATHAN S

ART UNIT

PAPER NUMBER

3732

MAIL DATE

DELIVERY MODE

06/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,811	MILES ET AL.	
	Examiner	Art Unit	
	Jonathan Werner	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/8/04 & 1/29/07</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 11/8/04 and 1/29/07 are noted. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Drawings

2. The drawings are objected to because the image quality of certain grayscale image reproductions makes it difficult to distinguish specific elements as referenced to in the accompanying specification. Such drawings include Figures 1, 6-8, 10-14 and 17-18. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6-9, 12-15 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As to claim 6, Applicant claims "at least one of said distraction assembly, one of said retractor blades, and said at least one shim member includes at least one stimulation electrode." However, as interpreted by Examiner, it is not clear if Applicant intends for each element (the distraction assembly, a retractor blade, and a shim member) to include said stimulation electrode, or if Applicant intended the claim to read as a Markush-type claim, wherein only one of said elements includes a stimulation electrode. Likewise, it is not apparent in claims 12 and 15 as to whether Applicant has intended the claim to read as a Markush-type claim as interpreted by Examiner. Claim 9 recites the limitation "said K-wire." There is insufficient antecedent basis for this limitation in the claim since Applicant did not positively claim the K-wire in claim 2. Instead, claim 2 merely sets out a limitation of a dilator by describing that it is capable of being slideably passed over such a K-wire –

hence the K-wire itself is not part of the system as claimed. Additionally, claim 18, which recites the limitation "said step of distracting from said distraction corridor," lacks sufficient antecedent basis for this limitation in the claim. Claim 19, which recites the limitation "said step of performing secondary distraction system," lacks sufficient antecedent basis for this limitation in the claim. Lastly, claim 20, which recites the limitation "said at least one stimulation electrode," lacks sufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 10-11 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathews et al. (US 6,206,826). With regard to claims 1 and 16, Mathews discloses a system for accessing a surgical target site comprising using a distraction assembly (i.e. D) with a handle for creating a distraction corridor to said target site; and a retractor assembly having a plurality of retractor blades (i.e. 10) which can be introduced simultaneously over the distraction assembly to the surgical target site (i.e. see Figures 21 and 26-27). As to claim 2, the distraction assembly shown in Figure 21 is capable of being slideably passed over a K-wire if desired (column 10, lines 52-58). As to claims 3 and 18-19, the assembly can include a plurality of sequential dilators

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(column 10, lines 59-65). With regard to claim 10, the system is intended to establish access to a spinal target site (see Abstract). As to claim 11, Figure 26 shows a posterior approach at establishing an operative corridor is a capable. As to claim 17, the guide pins (115) act as K-wires since they are intended for penetrating into the bone (column 9, lines 39-44). Examiner notes that Applicant has claimed instances of intended use and other functional statements throughout claims 1-15, i.e. claim 7 describes a control unit that is merely capable of electrically stimulating the electrode and sensing a response from the stimulation. Such statements do not structurally distinguish the claims over the prior art which is capable of being used as desired, and are hence given little patentable weight.

Claim Rejections - 35 USC § 103

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathews in view of Arthur (US 972,983). Mathews discloses the system as previously described above, but fails to show the dilator is a split-type dilator. Arthur, however, teaches a split dilator (i.e. see Figure 7-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to utilize a split dilator in order to increase efficiency make operation of the device easier as taught by Arthur (column 1, lines 14-17).

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6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathews in view of Koros et al. (US 6,139,493). Mathews discloses the system as previously described above, but fails to show the assembly includes a shim member coupled to the retractor blades, wherein the shim member includes an extension dimensioned to extend past the retractor blade into the surgical target site. Koros, however, teaches a retractor with such a shim member (i.e. 54) coupled to the retractor blades (i.e. 44). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to include a shim that extends past the retractor blade at the surgical site in order to allow adjustments to accommodate a wide range of patients as taught by Koros.

7. Claims 6-9, 13, 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathews in view of Koros and further in view of Underwood et al. (US 2001/0056280). As to claims 6 and 15, Mathews and Koros disclose the system as previously described above, but fail to show the assembly includes stimulation electrodes. Underwood, however, teaches a retractor for use in spine surgery (i.e. 278), wherein said retractor includes a stimulation electrode (112) positioned near a distal end of the distraction system (see Figure 13). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to include a stimulation electrode with the retractor in order to move, contract, and otherwise modify the tissue structures at the surgical site as taught by Underwood. As to claims 7-8 and 20, the system can further comprise a control unit which is capable of electrically stimulating the

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electrode, sensing a response from stimulation of a nerve or muscle, and communicating to a user (i.e. paragraphs 0058 and 0071). As to claim 9, Examiner notes that guide pins (115) of Mathews act as K-wires since they are intended for penetrating into the bone (column 9, lines 39-44). As to claim 13, the control unit of Underwood can comprise a display (i.e. 32).

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathews in view of Koros further in view of Underwood and yet further in view of Shin et al. (US 4,226,228). Mathews, Koros and Underwood disclose the system as previously described above, but fail to show the assembly includes a button on the handle. Shin, however, teaches a surgical retractor (i.e. 10) which includes a handle (i.e. 14) with a button (i.e. 18) on it. Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to include a button on the handle in order to make the retractor device less constricting as taught by Shin.

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathews in view of Koros further in view of Underwood and yet further in view of Streeter (US 6,273,905). Mathews, Koros and Underwood disclose the system as previously described above, but fail to show the control unit comprises a touch-screen display. Streeter, however, teaches a method for performing spinal surgery in which a control unit (i.e. 14) with a touch screen (i.e. 48) is used. Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to

include a touch screen in communication with the control unit in order for the practitioner to input data as taught by Streeter (column 4, lines 49-53).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 7,207,949 in view of Mathews et al. (US 6,206,826). Although the conflicting claims are not identical, they are not patentably distinct from each other because Applicant has primarily reworded or rearranged certain elements of the patented claims, except for the omission of a tubular distraction member. However, Mathews teaches a system for accessing a surgical site as described in detail in the rejection above, wherein the distraction member (D) shown

in Figure 21 is tubular. Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to make the distraction member tubular in order for another tool, such a reaming tool, to be extended through said distraction member during a procedure as taught by Mathews.

Conclusion

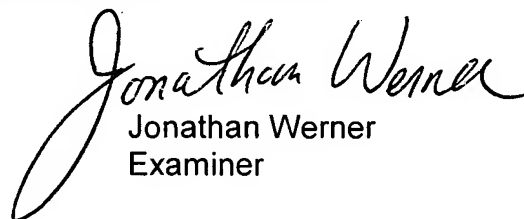
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please refer to included form PTO-892 for all additional pertinent prior art related to surgical access systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Werner whose telephone number is (571) 272-2767. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jonathan Werner
Examiner

5/24/07



Cary E. O'Connor
Primary Examiner